

Post-It Fax Note 7672

To Sameena Ahmed

Company

Location

Fax # 703-746-3967 Telephone # 703-308-3880

Comments

No. of Pages 3

Today's Date 3-1-02

Time

From Jonathan Scherer

Company Jacobson Holman PLLC

Location

Dept. Charge

Fax # 202-393-5350

Telephone # 202-638-6666

Original

Disposition:

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Here are the claims for PCT/GB99/00820,  
Serial no. 09/623,495, our Ref no. P65952USO

## Claims

PCT/GB99/00820

1. A method of drying, without damage, a compound which is subject to deactivation on drying, or a mixture of such compounds, comprising subjecting an aqueous system containing the compound or mixture to drying in the presence of one or more monosaccharide sugar alcohols and at least one additive which is a glass-former or a glass-formation-facilitator, whereby the compound solidifies from solution as an amorphous glass rather than by forming crystals.
2. A method according to claim 1 in which the aqueous system contains from 0.05 to 90% by weight of sugar alcohol.
3. A method according to claim 1 in which the ratio of sugar alcohol plus additive to compound is at least 0.25:1 preferably 0.5:1 by weight.
4. A method according to any of claim 1 to 3 in which the compound is a protein, polysaccharide or nucleic acid.
5. A method according to claim 4 in which the compound or mixture comprises an enzyme, serum, serum complement, an antibody or antigen (either free or coupled to a support), a nucleic acid, a fluorescent protein, or a vaccine component.
6. A method according to any of claim 1 to 5 in which the system is dried under conditions selected from one or more of the group consisting of ambient temperature or above, chill drying, freeze drying, spray drying, vacuum drying and drying at atmospheric pressure.

7. A dried product which is an amorphous glass containing monosaccharide sugar alcohol and at least one additive which is a glass-former or a glass-formation-facilitator and a compound which is subject to deactivation on drying, or a mixture of such compounds, in a weight ratio of sugar alcohol plus additive to compound of at least 0.25:1 preferably 0.5:1, the product having been dried.

8. A dried product according to claim 7 in which the compound is a protein, polysaccharide or nucleic acid.

9. A dried product according to claim 8 containing an enzyme, serum complement, an antibody or antigen (either free or coupled to a support), a nucleic acid, a fluorescent protein, or a vaccine component.

10. A method or product according to any preceding claim wherein the sugar alcohol is selected from the group consisting of mannitol, galactitol, xylitol, arabinitol and inositol.

11. A method or product according to any preceding claim wherein there is one or a mixture of additives selected from the group consisting of peptide, protein, borate ion, calcium lactate, phosphate, silicate and acetate salts.

12. A method or product according to claim 11 wherein at least one additive is selected from the group consisting of boric acid, tetraborate salt of sodium or potassium and sodium mannitoborate.

13. A method or product according to any preceding claim wherein the amorphous glass is formed from a mixture of 2 or more monosaccharide sugar alcohols.

14. A method or product according to any preceding claim wherein there is an additive which is a protein or denatured protein.

15. A method or product according to claim 1 or 7 wherein the amorphous glass is formed from a formulation having essentially a composition selected from:

1. mannitol 33.3%, inositol 33.3% and PVP 33.3%
2. mannitol 31.6%, inositol 31.6% xylitol 5% and calcium lactate 31.6%
3. mannitol 33.3%, inositol 33.3% and calcium lactate 33.3%
4. mannitol 33.3%, inositol 33.3% and Byco C 33.3%
5. mannitol 23.3%, inositol 23.3% calcium lactate 30% and PVP 23.3%
6. mannitol 33.3%, arabinitol 33.3% and calcium lactate 33.3%
7. mannitol 30%, inositol 15%, galactitol 15% and Byco C 409/0
8. mannitol 30%, inositol 15% galactitol 15% and calcium lactate 40%
9. mannitol 33%, Byco C 33% and calcium lactate 33%
10. mannitol 50%, and Kollidon 30 (polyvinylpyrrolidone (PVP)) 50%
11. mannitol 33%, Kollidon 30 (polyvinylpyrrolidone (PVP)) 33% and calcium lactate 33%
12. mannitol 50%, and Dextran 50%
13. mannitol 33%, Dextran 33% and calcium lactate 33%